REGARDING THE NEED FOR ARTIFICIAL PANCREAS

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OF WEST VIRGINIA

IN THE HOUSE OF REPRESENTATIVES

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Mr. RAHALL. Mr. Speaker, I rise today to call on the U.S. Food and Drug Administration to expedite its consideration of the artificial pancreas, a technology that will benefit those with type 1 diabetes.

Recently, I was visited by Lori and Jay Happala; Gina Frye; and Margaret Hoover at my office in Beckley, West Virginia, as part of the Juvenile Diabetes Research Foundation's Promise to Remember Me campaign.

These families and one of their children who is diagnosed with type 1 shared with me personal stories about what life is like for sufferers of type 1 diabetes, and how continued research and breakthroughs in technology can help improve management of this disease.

The Juvenile Diabetes Research Foundation and other clinical experts from organizations like the American Diabetes Association have indicated that an artificial pancreas has the potential to transform the lives of those with type 1 diabetes by automatically controlling blood glucose levels around the clock, enabling them to remain healthy until a cure is found. My constituents argue that this technology has the potential to help those with diabetes better manage their type 1 diabetes in a more cost efficient manner, as well as help them to lead more fulfilling, active lives and reduce the risk of further health complications like kidney failure and heart disease.

Before this technology can be made available, the FDA must approve next steps in the regulatory process to continue the development of artificial pancreas systems. Earlier this year, my colleagues and I wrote to the FDA, requesting a clear and reasonable regulatory pathway so that outpatient studies can proceed as soon as possible.

Recently the FDA committed to publishing draft guidance for public comment by December 1. On behalf of the millions of Americans with diabetes, I urge the FDA to issue this draft guidance in a timely manner, so that artificial pancreas technologies can be tested in an outpatient setting and be made available to those who need as expeditiously as possible. Continued delays may slow innovation that has the potential to dramatically improve the lives of those with diabetes.